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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,861	02/24/2004	Thomas P. Hedman	89188.0058	3669

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EXAMINER	
OLSON, ERIC	
ART UNIT	**PAPER NUMBER**
1623	
MAIL DATE	**DELIVERY MODE**
05/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,861	HEDMAN, THOMAS P.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,19-21 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-9* is/are allowed.

6)☒ Claim(s) *19-21 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted February 15, 2008 wherein claims 19-21 are amended and new claims 31-33 are introduced. This application claims benefit of provisional application 60/498790, filed August 28, 2003, and is a continuation in part of US application 10/230671, now pending, filed August 29, 2002, which claims benefit of provisional application 60/316287, filed August 31, 2001.

Claims 1-9, 19-21, and 31-33 are pending in this application.

Claims 1-9, 19-21, and 31-33 as amended are examined on the merits herein.

The terminal disclaimer filed on February 15, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on pending patent application 10/230671 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Priority

The US parent application 10/230671, filed August 29, 2002 and the provisional applications 60/498790, field August 28, 2003, and 60/316287, filed August 31, 2001, upon which priority is claimed fail to provide adequate support under 35 USC 112, first paragraph for the claimed subject matter of instant claims 1-9 and 19-21 of this application because these applications are not seen to disclose any methods of treating scoliotic spines according to instant claims 1-9 or of increasing permeability or cell

viability of intervertebral discs according to instant claims 19-21. Thus, the filing date of the instant claims is deemed to be the filing date of the instant application, February 24, 2004.

Applicant's amendment, submitted February 15, 2008, with respect to the rejection of instant claims 19-21 under 35 USC 102(e) for being anticipated by Slivka et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require the additional limitation that the treated intervertebral disk have been repaired or regenerated. Therefore the rejection is withdrawn.

Applicant's terminal disclaimer, submitted February 15, 2008, with respect to the rejection of instant claims 19-21 under the doctrine of obviousness-type double patenting for claiming the same invention as claims 24-29 of copending Application No. 10/230671, has been fully considered and found to be persuasive to remove the rejection as the terminal disclaimer is proper. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 15, 2008, necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-21 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slivka et al. (US patent 6812211, of record in previous office action) in view of Sato et al. (Reference of record in PTO-892).

Slivka et al. discloses a method of treating a pathological intervertebral disc wherein a crosslinking agent is administered to the disc in an amount sufficient to crosslink at least a portion of the proteins present in the disc. (column 3, lines 35-50) The crosslinking agents include enzymes such as lysyl oxidase that produce aldehyde groups on the surface of proteins. (column 7 line 60 – column 8 line 15) The crosslinking agent affects the nucleus pulposus, (column 4, lines 5-14) which is a collagenous tissue, and the proteins being crosslinked inherently include collagen. Furthermore, the therapeutic effects, concerning the increased permeability and fluid flux of the affected discs, and increased viability of cells in the central region of the intervertebral disc, are considered to be inherent properties of the method of introducing a crosslinking agent into the intervertebral disc, and do not serve to distinguish the claimed invention over the prior art. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration.

Slivka et al. does not disclose a method where the composition is administered specifically to an injured or failed intervertebral disk that has been repaired or regenerated.

Sato et al. discloses an *in vivo* trial of a tissue engineering scaffold fir the repair of vaporized nucleus pulposus in rabbits. (p. 366, left column, third paragraph) The scaffold was used to make an implant comprising cultured annulus fibrosus cells on an atelocollagen honeycomb scaffold. (p. 366 left column fourth paragraph – p. 366 right column first paragraph) These cell-containing scaffolds were implanted in the intervertebral disks of rabbits that had suffered injury to the disks by laser vaporization. (p. 367, left column paragraph 2 - right column paragraph 1) Rabbits that received the implants showed much reduced narrowing of the intervertebral disk compared to those not receiving the implant. (p. 368, right column, paragraphs 2-3, p. 369, figure 6)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of Slivka et al. on a damaged intervertebral disk after treating said disk with the method of Sato et al. One of ordinary skill in the art would have been motivated to combine these two methods because they are both known in the prior art to be useful for treating damaged intervertebral disks. One of ordinary skill in the art would reasonably have expected success because combining known prior art therapeutic methods that are useful for treating the same condition is ordinary and routine in the art.

Thus the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 19-21 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slivka et al. (US patent 6812211, of record in previous office action) in view of Desrosiers et al. (US patent publication 2004/0091540, cited in PTO-892).

Slivka et al. discloses a method of treating a pathological intervertebral disc wherein a crosslinking agent is administered to the disc in an amount sufficient to crosslink at least a portion of the proteins present in the disc. (column 3, lines 35-50) The crosslinking agents include enzymes such as lysyl oxidase that produce aldehyde groups on the surface of proteins. (column 7 line 60 – column 8 line 15) The crosslinking agent affects the nucleus pulposus, (column 4, lines 5-14) which is a collagenous tissue, and the proteins being crosslinked inherently include collagen. Furthermore, the therapeutic effects, concerning the increased permeability and fluid flux of the affected discs, and increased viability of cells in the central region of the intervertebral disc, are considered to be inherent properties of the method of introducing a crosslinking agent into the intervertebral disc, and do not serve to distinguish the claimed invention over the prior art. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration.

Slivka et al. does not disclose a method where the composition is administered specifically to an injured or failed intervertebral disk that has been repaired or regenerated.

Desrosiers et al. discloses a minimally invasive method for repairing a damaged or injured intervertebral disk by injecting an *in situ* gellable formulation into the disk. (p.

3 paragraphs 26-30) The formulation preferably comprises a polymer that is polymerized or crosslinked after being injected. (p. 3 paragraph 0034) Various polymers are used as the gelling polymer, for example chitosan or polypeptides including collagen. (p. 4 paragraph 0056)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of Slivka et al. on a damaged intervertebral disk after treating said disk with the method of Desrosiers et al. One of ordinary skill in the art would have been motivated to combine these two methods because they are both known in the prior art to be useful for treating damaged intervertebral disks. Furthermore, one of ordinary skill in the art would have expected the crosslinking agents of Slivka et al. such as glutaraldehyde or lysyl oxidase to additionally be useful for *in situ* crosslinking of the injectable collagen compositions described by Desrosiers et al. One of ordinary skill in the art would reasonably have expected success because combining known prior art therapeutic methods that are useful for treating the same condition is ordinary and routine in the art, and because Desrosiers et al. already describes crosslinking the disclosed injectable polymers *in situ*.

Thus the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Conclusion

Claims 19-21 and 31-33 are rejected. Claims 1-9 are seen to be allowable. Reasons for the indication of allowable subject matter are given below:

The claimed invention is seen to be adequately described and enabled by the specification. For example, the treatment of scoliotic spines according to the invention is disclosed on pp. 8-9 of the specification. The examples on pp. 20-29 demonstrate that the claimed treatment increases the stiffness and resistance to bending of the affected spine, parameters that would be expected to reduce or treat scoliosis. Therefore the claimed invention meets the requirements of 35 USC 112.

The claimed invention is also seen to be novel and non-obvious over the prior art. Although certain prior art references such as Slivka et al. are seen to teach a method comprising injecting a crosslinking agent into an intervertebral disk, The prior art does not disclose a method wherein this treatment is specifically practiced on a scoliotic spine. Furthermore, the state of the art for treating scoliosis involves physical reinforcement of the spine such as bracing or spinal fusion. One of ordinary skill in the art would not have considered a method of crosslinking the intervertebral disk to be obviously useful for treating scoliosis. Therefore the claimed invention is seen to be novel and non-obvious over the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
4/25/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623